(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution obtained after reconstituting the drug as directed in the labeling.

[42 FR 59866, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

§ 440.180g Penicillin G potassium tablets for solution.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Penicillin G potassium tablets for solution are composed of penicillin G potassium. Each tablet contains penicillin G potassium equivalent to 100,000 units, 200,000 units, or 250,000 units of penicillin G. The potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of units of penicillin G that it is represented to contain. Its loss on drying is not more than 1 percent. The penicillin G potassium used conforms to the standards prescribed by § 440.80a(a)(1), except sterility and pyrogens.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The penicillin G potassium used in making the batch for potency, loss on drying, pH, penicillin G content, and crystallinity.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: Potency and loss on drying of tablets collected during the time of tableting the batch; and, unless the tablets are packaged into dispensing-size containers immediately after they are compressed, or the manufacturer has submitted to the Commissioner, and it has been accepted, information adequate to prove that such tests are not necessary, loss on drying of the tablets collected during each day of packaging the batch.

(*2*) If the person who requests certification is not the manufacturer of the batch: Potency and loss on drying of the tablets collected during each day the tablets are being packaged into dispensing-size containers.

(ii) Samples required:

(*a*) The penicillin G potassium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) If the person who requests certification is the manufacturer of the batch: A minimum of 30 tablets. If, after tableting, such person packaged the batch into dispensing-size containers: 20 tablets collected at equal intervals during each day the tablets are packaged, except that this sample is not required if the tablets are packaged immediately after they are compressed or if the manufacturer has been exempted by the Commissioner from such requirement.

(*2*) If the person who requests certification is not the manufacturer of the batch (for the purposes of certification, a batch shall be that number of tablets filed by such person into dispensing-size containers during each day's packaging operations): A minimum of 30 tablets collected by taking single tablets at such intervals throughout each day of packaging the tablets that the quantities packaged during the intervals are approximately equal.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of tablets into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the iodometric assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 1 to the reference concentration of 1.0 unit of penicillin G per milliliter (estimated).

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, diluting an aliquot of the stock solution with solution 1 to the prescribed concentration.

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

[42 FR 59867, Nov. 22, 1977, as amended at 50 FR 19919, May 13, 1985]

Subpart C—Injectable Dosage Forms

§ 440.201 Sterile azlocillin sodium.

The requirements for certification and the tests and methods of assay for sterile azlocillin sodium packaged for dispensing are described in § 440.1a.

[47 FR 53349, Nov. 26, 1982]

§ 440.202 Sterile amdinocillin.

The requirements for certification and the tests and methods of assay for sterile amdinocillin packaged for dispensing are described in § 440.2a.

[50 FR 7766, Feb. 26, 1985]

§ 440.207 Sterile ampicillin trihydrate for suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile ampicillin trihydrate for suspension is a dry mixture of ampicillin trihydrate and one or more suitable and harmless buffer substances, stabilizers, suspending agents, and preservatives. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. It is sterile. It is nonpyrogenic. Its loss on drying is not less than 11.4 percent and not more than 14.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.0. The ampicillin trihydrate used conforms to the standards prescribed by § 440.7a(a)(1) of this chapter.

(2) *Labeling.* In addition to the labeling requirements prescribed by § 432.5 of this chapter, this drug shall be labeled ''sterile ampicillin for suspension.''

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The ampicillin trihydrate used in making the batch for potency, loss on drying, pH, ampicillin content, concordance, crystallinity, and identity.

(*b*) The batch for potency, sterility, pyrogens, loss on drying, and pH.

(ii) Samples required:

(*a*) The ampicillin trihydrate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch:

(*1*) For all tests except sterility: A minimum of 12 immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute as directed in the labeling. Using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single-dose container, or, if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute the resultant solution with 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), for the microbiological agar diffusion assay, or distilled water for the iodometric assay, to give a stock solution of convenient concentration.

(ii) *Assay procedures.* Use either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter, diluting an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter.

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter, except in paragraph (d) of that section, add 3 drops of 1.2*N* hydrochloric acid to both the sample and working standard solutions after the addition of 0.01*N* iodine solution. Dilute an aliquot of the stock solution with distilled water to the prescribed concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except in lieu of (e)(1)(i)(*a*), prepare the sample for test as follows: From each of 10 immediate containers,